

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-421V

UNPUBLISHED

HELEN CLARK,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: August 21, 2024

Special Processing Unit (SPU);
Influenza (Flu) Vaccine; Shoulder
Injury Related to Vaccine
Administration (SIRVA); Six Month
Severity Requirement

Maximillian J. Muller, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Katherine Carr Esposito, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT¹

On January 8, 2021, Helen Clark filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). The Petition alleges that she suffered a shoulder injury related to vaccine administration (“SIRVA”) as a result of an influenza (“flu”) vaccine administered on September 17, 2019. Petition at 1.

For the reasons discussed below, I find Petitioner is entitled to compensation.

I. Procedural History

Petitioner filed this matter on January 8, 2021, amending the claim six months later. Respondent filed a Rule 4(c) Report opposing compensation on November 14,

¹ In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

2022. Respondent's Rule 4(c) Report ("Report"), ECF No. 42. Respondent argues that Petitioner cannot meet the Table requirements for a SIRVA claim. *Id.* at 14-16. On March 8, 2023, Petitioner filed a motion for a ruling on the record in favor of the claim. Motion for a Ruling on the Record ("Mot."), ECF No. 36. Respondent filed a response on March 22, 2023. Respondent's Response to Petitioner's Motion for Ruling on the Record ("Opp."), ECF No. 47. Petitioner file da reply on March 27, 2022. Petitioner's Reply to Respondent's Response to Motion for a Ruling on the Record ("Reply"), ECF No. 48. The matter is ripe for resolution.

II. Factual Background

The medical records reveal that prior to her vaccination, Petitioner was a licensed practical nurse, but was disabled and unemployed during the relevant time periods for this case. Ex. 7 at 455, Ex. 4 at 28, 102. Her pre-vaccination medical history is significant for diabetes, congestive heart failure, and dyspnea. Ex. 3 at 3; Ex. 4 at 194, 882, 903. She also had breast cancer in 2017 and 2018 that resulted in left breast lumpectomy and left axilla sentinel node biopsy. Ex. 4 at 716, Ex. 7 at 531, Ex. 8 at 960. During Petitioner's inpatient stay for surgery, she experienced a presyncopal episode that resulted in a fall on January 31, 2018. Ex. 4 at 716. She reported left arm pain "from having been braced from her fall the night before".

Twenty-one days prior to vaccination, Petitioner began treating with primary care physician Dr. Sierra Pena. Ex. 4 at 978. She was admitted to the emergency room for shortness of breath, COPD exacerbation, hypoxia. Ex. 4 at 993, Ex. 8 at 2373, 2379.

Petitioner saw Dr. Pena for a post-hospital check on September 17, 2019, when she received the vaccination at issue. Ex. 3 at 2. The record states that the vaccine was administered in Petitioner's right shoulder. Ex. 3 at 2, Ex. 4 at 1009, Ex. 6 at 1, Ex. 7 at 1333. No reaction was noted at that time. Ex. 4 at 1005.

At 2:35 A.M. on September 18, 2019, Petitioner sent a message to Dr. Pena stating that she "got the flu shot while at the office...in my upper left arm and it was leaking down my arm, so a second one had to be administered to my right arm." Ex. 9 at 1. She also stated that her "left shoulder is in a lot of pain". *Id.*

Petitioner next reported shoulder pain on October 7, 2019, when seen by Dr. Pena for a health maintenance visit. Ex. 4 at 1006. She reported left arm pain "since [she] got the flu shot." *Id.* However, there is no indication that her pain was discussed, or any examination occurred. *Id.* at 1018.

On December 3, 2019, Petitioner reported left shoulder pain, requesting a referral to a bone doctor. Ex. 9 at 2. In a follow-up message, Petitioner wrote “I received the flu shot on my left upper arm in September” and “the liquid leaked out from my arm while the nurse was trying to inject it.... My left arm continued to hurt a lot” and “something is wrong ever since I had that ‘failed’ flu shot on my left arm.” *Id.* at 3.

Petitioner had a consultation at a bone and joint center on December 10, 2019. Ex. 7 at 1166-84. She reported left shoulder problems that started after a flu vaccine and “frequent episodes of aching pain with attempted use of the left shoulder” that shot down her arm. *Id.* at 1177. An examination showed stable passive ranges of motion, and she was diagnosed with impingement syndrome. *Id.* at 1181. A cortisone injection was administered at that time and physical therapy was ordered. *Id.* at 1184.

Petitioner reported shoulder pain on January 13 and February 6, 2020. Ex. 7 at 1185, 1193; Ex. 14 at 33. Both times she stated that the cortisone injection had helped.

Several months later, Petitioner began physical therapy for her shoulder on May 4, 2020. Ex. 5 at 7, 44, 48. At that time, she had limited range of motion, reduced strength, poor scapular position, and neural tightness. *Id.* at 46. She attended nine physical therapy sessions between May and August of 2020. *Id.* at 8-50. She was discharged on August 10, 2020, not having met her goals. *Id.* at 15-16.

Petitioner continued to report shoulder pain on September 18, 2020, stating physical therapy granted her “no relief”. Ex. 4 at 1047. On January 14, 2021, Petitioner again reported left shoulder pain and received a subacromial injection. Ex. 7 at 1245, 1254. An MRI of her left shoulder on March 30, 2021, showed mild osteoarthritis, tendinitis, and mild bursitis. Ex. 12 at 2. Petitioner report ongoing left shoulder pain throughout 2021. Ex. 11 at 38, Ex. 11 at 64. Further, she had a third corticosteroid injection on May 10, 2021. Ex. 11 at 64.

On June 29, 2021, Petitioner was seen by an orthopedic surgeon. Ex. 11 at 163-64. The record notes that she had ongoing problems with her left shoulder that began after a flu shot in September of 2019, with pain that shot down her arm along with numbness in some fingers. *Id.* at 163. She was diagnosed with adhesive capsulitis but was deemed not a surgical candidate.

On September 13, 2021, Petitioner saw another orthopedic surgeon for a second opinion. Ex. 13 at 6. She was diagnosed with left shoulder and upper extremity syndrome, left elbow cubital tunnel syndrome, Cushing syndrome, COPD, DHF, and a history of breast cancer. *Id.*

Petitioner has submitted two declarations in support of her Petition. In the first, she explained that she received a flu vaccine on September 17, 2019. Ex. 10. Further, she “immediately felt pain as clear fluid leaked all down my arm” and the administrator “was unable to deliver the rest of the vaccine as there was resistance”. *Id.* In the second, she detailed how the first vaccination attempt on failed and she experienced immediate pain. Ex. 16 at 1. Petitioner also described her course of treatment. *Id.* at 1-2.

III. Legal Standard

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding her claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner’s allegations must be supported by medical records or by medical opinion. *Id.*

In particular, a petitioner must establish that she suffered an injury meeting the Table criteria (*i.e.* a Table injury), in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. If a petitioner establishes a Table injury the burden shifts to respondent to establish a more likely alternative cause. Section 13(a)(1)(A), 11(c)(1)(C)(i), 14(a). If a petitioner cannot establish a Table injury, or she may pursue causation-in-fact under the legal standard set forth in *Althen v. Sec’y of Health & Hum. Servs.*, 418 F. 3d 1274, 1278 (Fed. Cir. 2005).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time frame;

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

In addition to causation, a petitioner must also meet the requirements establishing that the vaccine received is “covered” by the Program, the duration and severity of petitioner's injury, and the lack of other award or settlement.³ With regard to severity, a petitioner must show that she suffered the residual effects or complications of her injury or condition for more than six months after the administration of the vaccine. § 11(c)(1)(D)(i); see *Song v. Sec'y of Health & Hum. Servs.*, 31 Fed. Cl. 61, 65-66 (1994), *aff'd*, 41 F.3d 1520 (Fed. Cir. 2014) (noting that a petitioner must demonstrate the six-month severity requirement by a preponderance of the evidence).

A. Site of Vaccination

Respondent contends that although Petitioner alleges a left SIRVA, the vaccine records state she received the flu vaccine in her right arm – with only an abortive attempt to initially administer the vaccine in her left arm. Opp. at 14. Respondent's reading of the administration record is literally correct (see Ex. 4 at 1003 (stating the vaccine was administered in Petitioner's right arm)), but his argument does not take into account the totality of the evidence, which soundly supports a left-side vaccine-related injury.

The overall medical records, coupled with Petitioner's witness statement, establish that Petitioner consistently and repeatedly reported to treaters left shoulder pain that was caused by the *attempt* to administer a flu vaccine *in that shoulder*. See, e.g., Ex. 9 at 1 (record from September 18, 2019 stating that Petitioner's left shoulder was in pain following a failed flu vaccination); Ex. 4 at 1006 (reporting left shoulder pain “since I got the flu shot”); Ex. 9 at 3 (Petitioner reporting left arm pain “since I had that ‘failed’ flu shot on my left arm”).

³ In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. See § 11(c)(1)(A)(B)(D)(E).

These records provide sufficient evidence that a vaccination was at least *attempted* for Petitioner's left arm. And these efforts occurred before the vaccine was successfully administered in Petitioner's right arm. The subsequent treatment records gain strength as well given their temporal proximity to the date of vaccination, with communications describing the events less than twenty-four hours after vaccination.

Otherwise Respondent has not demonstrated that a SIRVA claim has as a prerequisite proof that the attempted vaccination was *completed*. Rather, it is sufficient that the vaccination effort resulted in needle penetration and antigen introduction to be deemed to have been "received," and the record suggests both occurred. (I also note there is no dispute that the vaccine is one that is covered by the Program, and a vaccine intended for intramuscular administration as well.)

B. Factual Findings Regarding a Table SIRVA

After a review of the entire record, I find that a preponderance of the evidence demonstrates that Petitioner has satisfied the QAI requirements for a Table SIRVA.

1. Petitioner Had No Prior Left Shoulder Condition or Injury that Would Explain her Symptoms

The first requirement for a Table SIRVA is a lack of problems associated with the affected shoulder prior to vaccination that would explain the symptoms experienced after vaccination. 42 C.F.R. § 100.3(c)(10)(i). Respondent claims that Petitioner had a history of problems with her left shoulder, including left axillary surgery related to breast cancer, osteoarthritis, diabetic neuropathy, and cubital tunnel syndrome. Opp. at 16-17.

Petitioner explained, however, that her prior treatment was unrelated. For example, the breast cancer treatment involved removal of the lymph nodes from the armpit area, and Petitioner distinguished her shoulder pain as being "in a completely different area from where I had the ... surgery..." Mot. at 12. Further, there was no reports of left shoulder pain in the nineteen months prior to vaccination. *Id.* Moreover, Petitioner consistently linked her shoulder pain to the failed vaccination in her left shoulder even within hours of the procedure. Ex. 9 at 1, 3. This provides further evidence that any prior condition does not explain the symptoms associated with Petitioner's SIRVA.

2. Onset of Petitioner's Injury Occurred within Forty-Eight Hours of her Vaccination

Petitioner's pain occurred within forty-eight hours of vaccination. Ex. 9 at 1. Respondent does not contest this aspect of Petitioner's claim. Accordingly, there is preponderant evidence that establishes the onset of Petitioner's left shoulder pain more likely than not occurred within 48-hours of vaccination.

3. Petitioner's Pain was Limited to her Left Shoulder

Respondent claims that Petitioner cannot establish that her pain was limited to her shoulder because she also reported pain in the left axillary area, and pain that extended beyond her shoulder into her elbow, forearm, and fingertips. Opp. at 17-18. While Respondent's argument has merit, it ultimately fails to rebut Petitioner's Table showing.

The record contains reports of non-shoulder pain that radiated down Petitioner's arm (Ex. 7 at 1177, Ex. 11 at 63), but at the same time consistently identifies pain in her left shoulder. Ex. 9 at 1; Ex. 7 at 1245. Petitioner's complaints, and the diagnoses, are consistent with other SIRVA injuries seen in the program, including adhesive capsulitis and tendinitis. Ex. 12 at 2.

Admittedly, pain reported in Petitioner's arm and fingers is likely unrelated to Petitioner's SIRVA. And Petitioner has a complicated history that includes various treatments (including surgery) for breast cancer. But such issues can be addressed when calculating damages. The mere existence of such record complaints does not defeat a showing that Petitioner not only did experience shoulder-specific pain, but that most of her complaints and treatment efforts were aimed at that. Accordingly, preponderant evidence supports this Table element as well.

4. There is No Evidence of Another Condition or Abnormality

The last criteria for a Table SIRVA state that there must be no other condition or abnormality which would explain a petitioner's current symptoms. 42 C.F.R. § 100.3(c)(10)(iv). Respondent does not contest this aspect of Petitioner's claim. Accordingly, preponderant evidence supports this Table element as well.

C. Other Requirements for Entitlement

In addition to establishing a Table injury, a petitioner must also provide preponderant evidence of the additional requirements of Section 11(c). Respondent does

not dispute that Petitioner has satisfied these requirements in this case, and the overall record contains preponderant evidence to fulfill these additional requirements. Petitioner has therefore established that she suffered a Table SIRVA. Additionally, she has satisfied all other requirements for compensation. I therefore find that Petitioner is entitled to compensation in this case.

Conclusion

In view of the evidence of record, I find that there is preponderant evidence that Petitioner satisfies the QAI requirements for a Table SIRVA. Further, based on the evidence of record, I find that Petitioner is entitled to compensation.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master